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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,770	07/02/2001	Edward M. Lichten	20013810-0003	4869

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EXAMINER
SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/898,770	LICHTEN, EDWARD M.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-65 are pending.

Election /Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group I, consisting of claims 1-4 drawn to an assay for monitoring hormone concentration in blood, classified in Class 435 subclass 4, for example.
- Group II, consisting of claims 4-19 drawn to a method to treat hormonal disorder in a mammal, classified under Class 514, subclass 866, for example.
- Group III, consisting of claims 20-35 drawn to a method to treat a disorder related to hormonal disorder in a mammal, classified under Class 424, subclass 565, for example.
- Group IV, consisting of claims 36-51 drawn to a method to restore hormonal balance in a mammal, classified under Class 514, subclass 909, for example.
- Group V, consisting of claims 52-64 drawn to a kit to treat hormonal disorder in a mammal, classified under Class 424, subclass 565, for example.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions encompassing claims in Groups I-V are unrelated to each other because they are directed to different inventions that are not connected in design, operation and/or effect. These methods are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the procedures encompassed in each one of the inventions of Groups I-V at the same time to practice just one procedure/method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for e.g., different inventions disclosed in the claims encompassing inventions in Groups II and III are methods to treat hormonal disorder or a disorder related to an hormonal disorder respectively. However, a method that would treat a disorder resulting from hormonal disorder (e.g., diabetes) would not necessarily also treat the hormonal disorder (e.g., treating diabetes by administering a hypoglycemic agent to an individual in need thereof would not treat the insulin disorder in the said individual).

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (i.e., class and subclass), and their recognized diverse subject matter, restriction for examination purposes as indicated is proper.

Species Election

4. This application contains claims directed to different composition/method comprised of a variety of components. Therefore, if the applicant elects any of Groups II-V above, the applicant must also make election of species by electing at least one species from each one of the following categories:

Category A, Category B comprised of one among sub-catagories a-e and Category C as follows:

A. Category A. Elect One therapeutic agent among those claimed in Claims 4(iv), 20(iv), 36 (iv) and 52.

B. Category B one of the group of diseases from the following subcategories a-e as follows:

a. The group comprising diabetes related diseases (e.g., cataracts, diabetic retinopathy, hyperglycemia, hyperinsulinemia, hypertension, obesity and sexual dysfunction) in claims 7, 23, 39 and 53.

b. The group comprising mental dysfunction diseases (e.g., Alzheimer's disease and dementia) in claims 7, 23, 39 and 53.

c. The group comprising cardiovascular and related diseases (e.g., hypercholesterolemia, hypertension and obesity) in claims 7,23, 39 and 53.

d. The group comprising sex hormone related diseases (e.g., hypogonadism, menopausal symptoms and hot flashes, osteoporosis, osteopenia, sexual dysfunction, thinning of the vaginal wall and vaginal dryness,) in claims 7, 23, 39 and 53.

e. Breast, cervical, or uterine cancer in Claims 7-8, 23-24, 39-40 and 53-54.

C. Elect only one mode of administering the therapeutic agent among buccal, implantation, inhalation, oral, parenteral, percutaneous, rectal, topical, transmucosal or vaginal claimed in Claims 11, 27, 43 or 57.

For example a responsive election of invention in response to the election requirement in this action might state, "Applicants elect the invention of Group II for prosecution and further make a species election for diabetes related diseases as group of disorder, insulin as the therapeutic agent, and percutaneous mode of administration for the said therapeutic agent.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

In accordance with 37 CFR 1.499, applicant is also required that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species [MPEP § 809.02(a)].

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a

petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

December 16, 2002

Jon P. Weber, Ph.D.
Primary Examiner